Message

From: McClure, Peter [mcclure@srcinc.com]
Sent: 5/5/2014 9:15:19 PM
To: Pratt, Margaret [pratt.margaret@epa.gov]
CC: Hogan, Karen [Hogan.Karen@epa.gov]; Rice, Glenn [rice.glenn@epa.gov]; Chiu, Weihsueh [Chiu.Weihsueh@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]; Melia, Julie [jmelia@srcinc.com]; Carlson-Lynch, Heather [hclynch@srcinc.com]
Subject: RE: RE: BPA#: EP-BPA-11-C-0018; Contract No. GS-00F-0019L; TO#: EP-B14C-00008: PROPOSED WORK PAHS #6-10

Margaret,
Thanks for the information.
Peter

Peter McClure, PhD, DABT
Senior Toxicologist
SRC, Inc.
7502 Round Pond Road
North Syracuse, New York 13212
315 452 8420 (T)
315 452 8440 (F)

From: Pratt, Margaret [mailto:pratt.margaret@epa.gov]
Sent: Monday, May 05, 2014 4:39 PM
To: McClure, Peter
Cc: Hogan, Karen; Rice, Glenn; Chiu, Weihsueh; Flowers, Lynn; Melia, Julie; Carlson-Lynch, Heather
Subject: RE: RE: BPA#: EP-BPA-11-C-0018; Contract No. GS-00F-0019L; TO#: EP-B14C-00008: PROPOSED WORK PAHS #6-10

Hi Peter,

Below are EPA responses to questions regarding PAHs 6-10. Karen also asked me to pass along to you that in order to get an estimate as to how long the Bayesian modeling will take, she will have to speak with Leonid to see when he might be available. She said it doesn't take much time once he is available, but the estimate is complicated by the fact that it is not yet known how many datasets need it, since we still need to work through how many datasets might have RPFs of zero.

Responses to questions regarding PAHs 6-10:

For the PAHs 6-10, the following input is needed from EPA:
Bayesian BMD for BaAC in study by Cavalieri et al. 1977—Although as a complete carcinogenicity study it is the most preferred design, the sole BaAC tumor appeared at 53 weeks, well after the BaP tumor response reached 90% at 41 weeks. Even if the BaAC tumor had occurred within the timeframe that the BaP group was active, it's relatively extreme to compare the lowest possible response (1/39) with a maximal response in the other chemical to estimate an RPF. There are two dermal initiation studies which have more appropriate BaP to PAH data (Slaga et al. 1978 and Wood et al. 1980), and we will use those instead of attempting to model the disparate Cavalieri data.

Confirmation that 14 wk data should be used for BaP and BaAC in i.v. study by Adervont and Shimkin 1940—Not needed. Given the two physiological route studies for BaAC, we will not do any new modeling or RPF derivations using non-physiological route studies.

Determination of whether or not to borrow BaP data from a study 1 year later, for two studies of BeAPE (Amin et al. 1985a and Rice et al. 1985a):
- Not for Amin et al 1985a. To the best of my knowledge, all BaP data from this lab used 20-week promotion protocols; Amin et al 1985a used a 30-week promotion period and didn't report results at 20 weeks. We have better options for this PAH, so again we're not desperate to use this and caveat it.
- For Rice et al. 1985a, we want to consider this issue further before responding as similar circumstances also show up for other PAHs.

Please let me know if you have questions. Will send along more as I have them.

Margaret

From: McClure, Peter [mailto:mcclure@srcinc.com]
Sent: Thursday, May 01, 2014 2:09 PM
To: Pratt, Margaret
Cc: Hogan, Karen; Rice, Glenn; Chiu, Weihsueh; Flowers, Lynn; Melia, Julie; Carlson-Lynch, Heather
Subject: FW: RE: BPA#: EP-BPA-11-C-0018; Contract No. GS-00F-0019L; TO#: EP-B14C-00008: PROPOSED WORK PAHS #6-10

Margaret,
Attached is a file with a summary of proposed work for PAHs #6-10. More to come.
We look forward to your response.
Peter

Peter McClure, PhD, DABT
Senior Toxicologist
SRC, Inc.
7502 Round Pond Road
North Syracuse, New York 13212
315 452 8420 (T)
315 452 8440 (F)